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Informed consent documents used in human subject research within the United States Air Force appear increasingly complex and lengthy based on the level of risk, or potential harm to a human research subject, and are rife with both medical and legal terminology. It becomes difficult to discern whether the intent of consent forms is to inform the patient or protect the researcher and organization from litigation. A literature review highlighted two observations: (a) consistently, every article published about consent forms concluded that these documents were too complex for the layperson; and (b) there is a gap in the literature concerning the readability of consent forms in military protocols.

Using a 1997 study conducted by Mader and Playe ($n = 94$) as a foundation, this study evaluated the readability of consent forms ($n = 21$) in human research performed within the United States Air Force. Studying the effects of ten dependent variables based on two levels of risk (minimal risk and greater than minimal risk), we found significance across three of ten variables with Air Force consent forms ($p < .01$). Validity of the study was strengthened by similarities with the results of Mader and Playe (1997).

The results demonstrate that the readability of consent forms within the U.S. Air Force is too complex for the average reader. A readability standard of the sixth grade level is difficult to meet, but such a standard would better serve the interests of participants in human subject research to understand the methods, risks, benefits, and alternatives of the research. The Nuremburg Code (1947), the Belmont Report (1976), and the Declaration of Helsinki (1964/2000) demand that the rights of individual patients and human research subjects be placed above scientific and societal goals. I argue that when subjects of studies cannot understand the contents of a consent form, their autonomy is not respected

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Running head: READABILITY OF CONSENT FORMS IN HUMAN RESEARCH

Exploring the Readability of Consent Forms in Human Research in the United States Air Force

Graduate Management Project

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U.S. Army-Baylor University Graduate Program in Health Care Administration

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Introduction

The introduction, literature, purpose, and procedure sections of this study have been co-authored with CPT Heidi Mon. These sections are mirrored exactly as written here in her study.

During our second semester of the U.S. Army Baylor Program, CPT Mon and I conducted an independent study under the direction of Dr. Karin Zucker, Associate Professor. This study involved performing a comprehensive literature review of the readability of informed consent documents in the conduct of human research within the Department of Defense (DoD). While an abundance of literature exists on readability of informed consent documents in the civilian sector, there was little found involving DoD. The lack of literature prompted this current study.

In order to compare the results involving the United States Army and Air Force informed consent documents and to verify the validity and reliability of the comparison, the study conducted on the respective service's consent forms had to be identical. Therefore, CPT Mon and I co-authored the purpose and procedure sections which now appear in our respective studies. Further, we maintained communications throughout our respective studies to ensure that any difficulties encountered during the performance of the studies were handled in the same fashion.

Conditions That Prompted the Study

When we attended the Institutional Review Board (IRB) at Brooke Army Medical Center (BAMC) we found the consent forms included with the protocols were complex and lengthy. When the risk to a subject was high, the complexity and length of the consent forms seemed to increase. All were rife with both medical and legal terminology. It became difficult to discern whether the intent of consent forms was to inform the patient or protect the researcher and

organization. A brief literature review highlighted two observations: (a) consistently, every article published about consent forms concluded that these documents were too complex for the layperson; and (b) there is a gap in the literature concerning the readability of consent forms in military protocols. A comprehensive literature review ensued on the readability of consent forms in military, human research studies.

Statement of the Problem or Question

The primary question was, "What is the readability of consent forms in military, human research studies?" To answer this question, it was necessary to: (a) operationally define readability, (b) discern the intent of the consent form in human research, and (c) explore the ethics inherent to this subject. Overall, the observation was that the reading level of consent forms is too high. Reading levels above the average person's ability do not facilitate his/her understanding of the research procedures and their risks, benefits, and alternatives to the research procedures. Supporting studies to this claim include Glazer-Waldman, Hall and Weiner's research (1985) that demonstrated 40% of adults tested at a Texas hospital read below the 6th grade, and Ott and Hardie's study (1997) that suggested written materials given to patients should not be above the sixth grade level. Using the previously mentioned studies and the guidance provided in Army Regulation 40-38 (The Clinical Investigation Program) that consent forms "will be written in language that is easily understandable by the subject," the average person's ability is defined as sixth grade for purposes of this study (Army Regulation 40-38, 1989, p. 4).

Literature Review

The History of Informed Consent

Scrutiny of human subject research exposes a sinister side to medical research and a long

history of grossly unethical experiments performed on non-consenting patients, even though its regulation reaches back to World War II when the horrific Nazi experimentation was exposed. Following the Second World War, the United States tried and executed a number of involved Germans for war crimes and crimes against humanity in what became known as The Doctors' Trial at Nuremberg. (*United States v. Karl Brandt*, 1947). The opinion in that case included 10 basic principles for human research, called the Nuremberg Code. Thereafter, Article seven of *The Universal Declaration of Human Rights* was passed to protect research subjects from torture, and cruel, inhumane treatment (The United Nations General Assembly, 1948). Later, the World Medical Association published *The Declaration of Helsinki (1964)* that safeguarded the health of the subjects (as cited by Zucker & Boyle, 2000). Finally, the *Belmont Report* (1976) stood as ethical principles and guidelines for the protection of human subject research. Together, the Nuremburg Code of 1947 and the Declaration of Helsinki of 1964 formed the basis of United States federal regulations that govern federally supported research with human subjects (Woodward, 1999). Both codes demanded that the rights of individual patients and human research subjects be placed above scientific and societal goals. Yet, the experimentation without informed consent continued.

Several notorious cases of unethical human experimentation tarnish America's rich history of medical advancements. The Tuskegee Experiment, from 1932 through 1972, involved 399 unknowing African American participants in a study involving the effects of untreated syphilis (Jones, 1993). In 1952, Harold Blauer was subjected to injections of mescaline derivatives supplied by the U. S. Army Chemical Corps. The purpose of the injections was to determine the effects of chemical agents on humans, but they were administered to Mr. Blauer under the guise they would cure his depression (Albarelli & Kelly, 2001). In 1953, without parental consent, a

premature infant was given a high dose of oxygen as part of an experiment. The infant went blind (Standler, 1997). In 1963, 22 chronically ill non-cancer patients unknowingly received intradermal injections of live human cancer cells. The experiment's purpose was to learn if foreign cancer cells would survive longer in incapacitated non-cancer patients than in patients debilitated by cancer (Standler, 1997). In 1964, personnel at the Willowbrook State Hospital in New York injected severely retarded children with hepatitis virus. The parents 'consented' to the injections believing they were vaccinations (University of Utah, 2004). From 1960 to 1972, cancer patients in Cincinnati were exposed to large doses of whole body radiation as part of an experiment, although they thought they were receiving standard treatments. Several died prematurely as a result of radiation exposure (University of Utah, 2004.).

In 1974, the National Research Act established the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. During the next 4 years, the commission identified the basic ethical principals that should underlie the conduct of biomedical and behavioral research involving human subjects. Additionally, it recommended guidelines to ensure that the research was conducted in accordance with those principles. On September 30, 1978, the commission submitted a report defining the basic ethical principles in human subject research titled The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research (Beauchamp & Childress, 2001).

The Belmont Report set forth the three requirements essential for the ethical conduct of research involving human subjects: autonomy (respect for persons), beneficence, and justice. The report also defined how these principles apply to the conduct of research. The principle of autonomy (respect for persons) underlies the need to obtain informed consent (Beachamp & Childress, 2001). Informed consent provides a primary means by which federal regulations

pertaining to human subject research seek to protect the rights and welfare of research subjects (Woodward, 1999).

Informed consent includes three elements: information, voluntariness, and comprehension, (U.S. Department of Health and Human Services, 2004). Enough information must be provided to potential research subjects for them to decide whether to participate in the research. Elements of essential information include: the purpose of the research, expected duration of the subject's participation, description of procedures and which procedures are experimental, description of reasonably foreseeable risks or discomforts to the subject, potential benefits, alternative procedures that might benefit the subject, extent of confidentiality, explanation of compensation, a point of contact for additional questions, a point of contact if injury occurs, a statement of voluntariness, a statement of reassurance that failure to participate will not cause penalty or loss of benefits to which the subject is otherwise entitled, and a statement of reassurance that the subject can discontinue participation at any time without penalty of loss of benefits (CFR 45.46.116, 1991). Consent to participate in research must be completely voluntary in nature and free from coercion. Finally, study participants must be able to comprehend the information presented to them. "The presentation of information must be adapted to the subject's capacity to understand it; testing to ensure that subjects have understood may be warranted" (U.S. Department of Health and Human Services, 2004).

An abundance of literature urges researchers to write simple and brief consent forms, yet consent forms range in complexity from grade 6 through grade11 and beyond. Although the process of informed consent involves more than the written consent form, the basics of the research are first defined in the consent form; and, thus, it forms the basis for the potential participant's ability to comprehend the purpose, procedure, risks, benefits and alternatives risks,

and then volunteer for participation. The readability of a consent form is vital to obtaining informed consent in human subject research.

Assessing Reading Level

The term readability refers to all the factors that affect success in reading and understanding text including the interest level and motivation of the reader, the legibility of the print, and the complexity of words and sentences in relation to the reading ability of the reader (Johnson, 2004). The determination of readability addresses the problem of matching individual reading levels to the difficulty of the text.

Several tests exist to assess readability or reading level. The primary purpose of these tests is to provide an assessment of the density of the text. The Gunning Fog Index uses the number of words per paragraph, the number of sentences per paragraph, and the number of words with three syllables or more to determine the number of years of education needed by the reader to understand the text. Shorter sentences written in plain English score better than longer sentences written in complicated language (Gnome, 2004).

The Flesch-Kincaid Formula assesses grade level and reading age by determining the average sentence length and the average number of syllables per word. Similar to the Flesch-Kincaid Formula, the McLaughlin Simplified Measure of Gobbledygook (SMOG) readability formula computes readability based on the average number of syllables per word and the average number of words per sentence. However, the SMOG formula computes a reading level for written materials that is not associated with a grade of school such as that calculated by the Flesch-Kincaid Formula (University of Utah, 2004). Additionally, the McLaughlin Formula tends to calculate higher values than other readability formulas because this test intends to predict the level necessary for 100% comprehension of the text (Johnson, 2004).

The Fry Readability Graph uses the average number of sentences and the average number of syllables per 100-word passage. These averages are then applied to the Fry graph to determine reading age in years. The Powers-Sumner-Kearl Formula is most suitable for analysis of material for 7 to 10 years old readers, and it uses the average sentence length (number of words /number of sentences) and the number of syllables per 100 words to determine reading age. The FORCAST Formula was specifically designed for assessing the readability of U.S. Army technical manuals. As such, it is not suitable for primary age reading material (Johnson, 2004). This formula does not require full sentences to access readability. Grade level is calculated by dividing the number of single-syllable words in a 150-word passage by 10. This number is then subtracted from 20. Reading age is determined similarly by subtracting the number of single-syllable words divided by 10 from 25 (Johnson, 2004).

There are several limitations to assessing reading level by any readability test, however. First, a readability test predicts the 'break-off' point for a reader of a specific reading age (Johnson, 2004). If a reading level is measured at 10^{th} grade, an average 10^{th} grader would be at the upper limit of his/her reading comprehension. Most readability formulas are based on a 50% correct answer score in a comprehension test (the McLaughlin SMOG formula is an exception). If a reading level of 10 years was predicted, an average 10-year-old student would only score 50% on a test of comprehension of that text (Johnson, 2004). Readability tests alone may not be the only evaluator of the suitability of text, which is another limitation. Other factors may need to be considered such as the size of type and length of line, sentence structure, the number of words per page, the use of color, the use of diagrams, the page layout, and the use of space between paragraphs (Johnson, 2004).

The concept of readability is based on "functional literacy" (Lee, 1999). Individuals not

only need to be able to read, but also to understand and act on that understanding, especially when considering the risks and benefits of participation in a human subject research study. In response to the scrutiny of readability of patient material, three specific tests were developed within the last few years to evaluate medical literacy. The Rapid Estimate of Adult Literacy in Medicine (REALM) was designed for use in public health and primary care settings to identify patients with low reading levels. A second test is the Test of Functional Health Literacy in Adults (TFHLA). This test more fully assesses functional literacy as well as reading ability. Analyses indicate that results of this test correlate with scores on more generalized reading tests.

Readability of Informed Consent Documents

The Declaration of Helsinki requires human researchers to "adequately inform" participants concerning the trial's aims, methods, expected benefits, risks, and alternatives. Unfortunately, the authors of the Declaration failed to define the elements of adequate information. The writers also did not describe the end state of being adequately informed. Informed consent received considerable attention by Beauchamp and Childress (2001). These icons of medical ethics defined informed consent as "an autonomous authorization of individuals of a medical intervention or of involvement in research" (p. 78). Meisel and Roth (1981) and the Belmont Report (1976) posit (as referenced by Beauchamp & Childress, 2001, p.79) two of the elements of informed consent are *information* and *consent*. Information is not merely disclosure of information but is also comprehension of what is disclosed (Beauchamp & Childress, 2001). Consent is more complicated. This latter element consists of five elements: (a) competence, (b) disclosure, (c) understanding, (d) voluntariness, and (e) consent (p. 79). These building blocks create a pyramid of consent, the absence of which makes the structure unstable. "One gives and informed consent to an intervention if (and perhaps only if) one is competent to act, receives a

thorough disclosure, comprehends the disclosure, acts voluntarily, and consents to the intervention" (p. 79).

The rules and regulations of the U.S. Department of Health and Human Services instruct the authors of consent forms to write these documents using language that is understandable by the subject; the Public Welfare Title of the Code of Federal Regulation (CFR), however, does not specify a readability standard by established indices (Public Welfare, 2004). In order for a consent form to adequately inform a participant, the consent form must use language commensurate with his ability to read and comprehend. Pursuant to this intent, researchers such as Mader and Playe (1997) explored standards set by institutional review boards (IRBs). Esty, Musseau, & Keehn (as cited in Mader and Playe, 1997) claim a preponderance of IRBs interpret the Code of Federal Regulation's instruction as a readability scale no higher than the sixth grade.

Ferguson (2002) explored medical trial participants' perceptions of the adequacy of the information they were provided and their understanding of this information. Participants in Ferguson's study felt they understood the experiment's intent, methods, benefits, risks, and alternatives. The participants even felt they had adequate time to ask questions. When they were questioned about the study, however, the depth of their understanding was shallow. Ferguson referenced Howard and DeMets' (1981) findings that, "research subjects . . . do not adequately understand the programs involved" (p. 48). Researchers focus on providing information, but few seek to ensure that the participants understand what they were provided (Ferguson, 2002). Arthur (1995) explored the effects of repeated exposure to medical information by providing an additional pamphlet to patients upon their discharge to increase the frequency of their exposure to the details of the experiment. She found a statistically significant increase in recall of the medical information concerning specific conditions and medications. The research of Ferguson

and Arthur demonstrated that repeated exposure to the information in consent forms might increase the participants' recall of the information, but not necessarily their level of understanding. The first principle in the Nuremburg Code (as referenced by Zucker, 2000, p. 845) requires that the participant "should have sufficient knowledge and comprehension of the elements of the subject matter involved as to enable him to make an understanding and enlightened decision." Because participants must be able to read and understand the details of the experiment, a readability assessment of the consent form should be used as a measurement tool.

The seven readability assessments in the literature are not immune to criticism. Some researchers question the validity of the readability tests. Others challenge the readability thresholds set by tests. Furthermore, different researchers set dissimilar readability thresholds, and their range is wide. The science behind the selection of readability parameters is not exacting in nature.

Three studies exemplify the wide range of readability thresholds. Ott and Hardie (1997) cited the Flesch reading ease score as the U.S. Government standard for military documents and specified its readability goal of seventh to eighth grade (based on a readability score between 60 and 70). Despite their reference to the U.S. Government standard, Ott and Hardie set their readability threshold at the sixth grade. Arthur (1995) evaluated the readability of medical pamphlets in the United Kingdom. His literature review expressed the importance of discernment and caution when interpreting the results from various readability assessments. He found that the algorithms used by the tests are complex and can render a wide range of reading ages. Using the Flesch, FOG, and SMOG indices, Arthur set an acceptable readability level at 11.6 years of schooling. Mader and Playe (1997) set their readability goal at fifth grade but offered little

justification for their choice.

How low a researcher should set his readability-criteria threshold in order to ensure a high percentage of adequately informed participants is still unclear. Researchers should select thresholds commensurate with their audience. Arthur (1995) found many pamphlets written at a readability score of 15. Clearly, this threshold is too high for most readers. Glazer-Waldman, Hall, and Weiner (1985) found 40% of adults at a Texas hospital read below the sixth grade level. Ott and Hardie cited research by Walmsley and Allington (1982) that found 33% of elderly adults at a New York senior center read below the fourth grade level and 35% read between the fifth and eighth grade level. Although Mader and Playe (1997) set their readability goal at fifth grade, they found the readability average of the medical material they evaluated was above a 10th grade level. Almost universally, Walmsley and Allington (1982), Mader and Playe (1997), Glazer-Waldman, Hall, and Weiner (1995), Ott and Hardy (1997), and Ferguson (2002) agreed that the consent forms they evaluated were written at a level above the participants' ability to comprehend their message. Such conclusions question the ability of most consent forms to adequately inform participants of risks, benefits, and alternatives.

Another common criticism of the various readability assessments is that researchers cannot equitably compare their results without a baseline understanding of the indices. Mader and Playe (1997) assessed readability using Right-Writer 5.0, which is a program that checks documents for grammar and spelling. This program is comprised of three indices: Flesch-Kincaid, Flesch, and Gunning Fog. These indexes all provide readability levels that have become industry standards, but each bases its conclusion on distinct algorithms. The resulting readability level for each test cannot necessarily be compared with the results of the other two. Other researchers use different readability programs that calculate similar indices. Ott and Hardie

(1997) evaluated the readability of advance directives using another program, similar to Right-Writer 5.0, Grammatik II. This program also calculated the readability scores of Flesch, Flesch-Kincaid, and Gunning Fog indices. Their study evaluated the scores against each other. According to the Grammatik II program results, the Flesch and Gunning Fog indices consistently provide higher readability scores than the Flesch-Kincaid index. Ott and Hardie did not interpret the results, provide reasons for the difference, or suggest one test over the others. Instead, the researchers left such conclusions to the reader. Such inconsistent results reinforce concerns about the reliability of the tests.

Researchers complain that they must provide a vast amount of information to a population that will most likely not be able to understand it (Ferguson, 2002). They must fulfill the requirements of the Nuremburg Code, the Universal Declaration of Human Rights, the Declaration of Helskini, and the Belmont Report. The complexity of the requirements creates the potential for an intricate and complex document.

Ferguson (2002) highlighted the bifurcated role that researchers must play by describing the direct relationship between the extensive nature of the consent process and the resulting satisfaction of the participants. Participants appreciated the extent of the information and felt it was necessary for their understanding (Ferguson, 2002). Whether the information increased the their understanding of the consent material was unknown. Further studies are needed to assess the validity of participants' perception of their understanding (Ferguson, 2002). Ferguson's research stresses the importance of conveying a complete message to the participants of human research during the consent process. A consent form authored with an appropriate level of readability enables the participant to better understand the elements and effects of a study. A participant that fully understands a study helps the researcher meet the Declaration of Helsinki's

requirement of *adequately informed consent.*

Relying on a report from the Health Journal of Family Practice which stated that "almost half of American adults read at or below the 8th grade level" (1988), members from a group of IRBs developed a set of consent form templates for researchers to use (Paasche-Orlow, Taylor, & Brancati, 2003). These templates ranged in readability from 4th grade to college level and were developed to assist researchers in writing consent forms at a level that most participants can understand. The IRBs provided these templates to medical schools and research institutes (Paasche-Orlow, Taylor, & Brancati, 2003). They serve as an excellent resource today for researchers trying to simplify the language of their consent forms. A combination of these templates and common readability assessments should provide researchers a tool that will allow them to improve readability and comprehension. Improved readability should enable participants to better understand the details of the study, benefits, risks, and alternatives.

Autonomy and MHS Protocols

Beauchamp and Childress (2001) require five elements to satisfy the bioethical tenet of autonomy. They require liberty, which is the "independence from controlling influence," and agency, which is the mental "capacity for intentional action" (p. 58). The other three required elements, inherent to respect for autonomy, explain that normal choosers are those who act "(1) intentionally, (2) with understanding, and (3) without controlling influences that determine their action" (p. 59).

The vast amount of literature that discusses the need to improve the readability of consent forms begs the question: Why do researchers continue to author consent forms far above the readability level of average participants? Exploring that question is beyond the scope of this study. A more focused question for this study is: How widespread is the problem within the

military health system (MHS)?

The Department of Defense (DOD) conducts a large amount of human subject research every year. 10 USC 980 requires that funds appropriated to the Department of Defense may not be used for research involving a human being as an experimental subject unless (1) the informed consent of the subject is obtained in advance; or (2) in the case of research intended to be beneficial to the subject, the informed consent of the subject or a legal representative of the subject is obtained in advance. The Secretary of Defense can waive these requirements with respect to a specific project if the project's purpose is to advance the development of a medical product necessary to the armed forces and if the research project may directly benefit the research subject and is carried out in accordance with all other applicable laws.

. DOD human research studies solicit participants from the MHS community, to include retirees and trauma patients brought into MHS emergency rooms. Human subject research within the Department of Defense is divided into minimal risk studies and greater than minimal risk studies. Minimal risk studies, as defined in Part 219 of 32 Code of Federal Regulation, Protection of Human Subjects, are studies where the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests (National Defense, 2004). Greater than minimal risk studies are those outside the studies defined as minimal risk. Degree of risk is established by following the guidelines in 32 CFR Part 219 and Army Regulation 40-38. AR 40-38 (1989) instructs investigators to author volunteer agreements "in language that is easily understandable" (3-5.(6).c.3), language that is not otherwise defined.

Military consent forms written to a participant from a military community should adopt a readability standard, such as that used in Mader and Playe (1999). A readability standard of the sixth grade level is difficult to meet, but such a standard would better serve the interests of the participants. This study explores the readability of consent forms for human subject research studies of minimal and greater than minimal risk conducted by MHS researchers in active duty military treatment and research facilities.

Intent of Consent Forms

The intent behind a reasonably understandable consent form is to enable the participant to weigh the benefits against the risks and alternatives inherent in the research design. This decision process is necessary to empower the participant with autonomy (Luce, 2003). Because "every human being of adult years and sound mind has the right to determine what shall happen to his body" (*Schloendorff v. Society of New York Hospital*, 1914), the consent form plays an integral role in the consent process.

It is worthy of note that in most cases, the consent form is not the primary method of informing the participant of the details of the study and the inherent benefits, risks, and alternatives – it is certainly not the sole means. The consent form is combined with an interview, a question and answer period, and often a video – all, not infrequently, followed by additional face-to-face discussions during the consent process. Researchers should attempt to tailor the entire consent process, particularly the readability of the consent form, to their audience. The participants' ability to comprehend may be reduced by medical conditions. Participants in psychiatry or oncology studies could be particularly vulnerable in this regard. Not only is each patient adjusting to a potentially life-altering sickness, but he must also endure a consent process laden with complex medical and legal terminology.

Oncology consent forms are inherently lengthy. The authors of oncology consent forms must satisfy a group of stakeholders, which includes the hospital attorney, the researcher himself, and the members of the IRB. The legal review balances due diligence with institutional protection. The researcher himself weighs anonymous advancement of his science with his desire for recognition and advancement in his field. The IRB weighs the risks of the trial with the potential benefits. The ethical intent of the researcher should be to use the consent form to facilitate autonomy, and this intent should rest equally on all shoulders.

Luce (2003) questioned the applicability of the consent process in deference to the psychological state of critically ill patients. He explored the legal competence of the critically ill and discussed the absence of legal surrogates. If a patient is otherwise competent, does his critically ill status alter his ability to make decisions on his own behalf? Does the mental state subsequent to a grim diagnosis and dim prognosis of life expectancy create in the patient indifference to risk in light of remote benefit?

Patients automatically assume the physician has their best interests at heart. Many doctors do have such altruistic motives, but the few who do not raise several questions. At what point do professional notoriety and advancement and the possibility of monetary gains change altruism into self-interest? At what point does a seasoned researcher become aware of his changing motives and sense ambivalence? Does such extreme self-interested motives affect the research, the consent process, or the participants' autonomy?

The literature suggests a consistent trend in the readability of consent forms. The psychological state of critically ill patients that creates indifference in their decision-making process may perpetuate this trend by reinforcing a sloppy consent process. If the patients' desperation supports the researchers' ambition, are the ethics of the situation compromised? Is

the emphasis on autonomy as defined by Beauchamp and Childress not-applicable in palliative care? If there has been no improvement in the readability of consent forms in 30 – 40 years, is it because the medical community has not focused on the issue, or is it because many patients do not care about the risks involved in a study if there is even the possibility of only a modicum of benefit?

If a researcher authors a consent form above an acceptable level of readability, is he abiding by the Declaration of Helsinki's requirement to adequately inform participants? Perhaps he is, if the complicated consent form is adequately explained during the consent process.

The results of this study support the trend noted in the literature, i.e., that consent forms for human research are written above the level of comprehension of the average participant. Researchers' may compensate for the imbalance of readability with complexity in the rest of the consent process, or it may not be.

Matot, Pizov, and Sprung (1998) studied the legitimacy of the human research process. 45 CFR Part 46, or *The Common Rule*, requires that anybody who receives money from the federal government to perform human subject research must follow the Department of Health and Human Services published regulations for the protection of human subjects. Though the Common Rule requires the IRB process for human research (Zucker & Boyle, 2000), Matot, Pizov & Sprung found that 41% of the 279 research studies they reviewed involving critically ill patients were either not reviewed by an IRB or the issue of informed consent was not addressed (1998). Though the Declaration of Helsinki compels medical journals to decline to publish research without IRB approval or informed consent, many journals still publish the research (Matot, Pizov & Sprung, 1998). If the Nuremberg Code, the Declaration of Helsinki, the Belmont Report, and the Common Rule require adequate informed consent, why has there been

no improvement in level of readability of consent forms? Perhaps the reason for this trend transcends blind, generational mentoring. Could a justification for complex consent forms stem from a medical professional's desire to advance in his field? Professional associations such as the American College of Healthcare Executives, the American Association of Medical Assistants, and the Association of Medical Surgeons of the United States facilitate the dissemination of information and networking. A professional's ability to attain name recognition largely originates with publication in widely read, peer-reviewed journals. Would a more exhaustive, simpler-to-understand consent form enable a participant to properly weigh the dismal probabilities of benefit against the high probability of harm? If this Spartan message were conveyed to the participant, would the researcher find sufficient numbers for statistical significance? Does a person's desperation become the deciding factor for participation in a Phase I study? Does desperation replace reason when evaluating the study's risks and benefits? Will the researchers in Phase I studies ever see a decrease in participation? If research participants became more reticent about participating in medical research trials, would research institutes be able to process the volumes of data necessary for future funding? Perhaps self interest fuels the narcissistic motivation for a sloppy consent process.

Purpose (Variables/Working Hypothesis)

This study examines the readability statistics based on the risk or potential harm to a human research subject. The two risk categories in military human subject research, as defined by the Common Rule and Army Regulation 40-38, are minimal risk and greater than minimal risk. The readability statistics are calculated using Microsoft Word™, which utilizes the Flesch-Kincaid criteria. Consent form readability variables includes the Flesch Reading Ease, Flesch-Kincaid grade level, number of words per document, number of characters per document,

number of paragraphs per document, number of sentences per document, average number of sentences per paragraph, average number of words per sentence, average number of characters per word, and number of passive sentences per document. These statistics are quantitative in nature, enabling statistical analysis on the Statistical Package for the Social Sciences (SPSS™) version12.0. The alternate hypothesis is that the readability of consent forms in military protocols is sufficient to adequately inform the average military reader (Flesch-Kincaid grade level of 6). The null hypothesis is that the readability of consent forms in military protocols is too complex to adequately inform the average military reader (Flesch-Kincaid level of 6).

Method and Procedures

Mader and Playe (1997) explored the readability of consent forms used in emergency medicine research. Their method served as a foundation for this initial pilot study. Mader and Playe chose a descriptive, two-factor research design to compare the readability indices of consent forms (n = 94) over three categories separated by level of risk. The researchers analyzed the means of the groups with ANOVA and the Kruskal-Wallis test. They reported that the readability necessary to understand the consent forms rose as the risk of the study changed. Their results were significant ($p = .03$).

Procedures

For the pilot and full study, the Chiefs of the Clinical Investigation Regulatory Office of the Army and the Air Force were contacted and asked to provide copies of consent forms over the time period 1999 – 2003. We anticipated some consent forms would be provided in hard copy while others would be in Adobe Acrobat™ (.pdf) files. Hard copy consent forms were scanned using commercial optical character recognition (OCR) software. Graphical and character mistakes from the scanning process were manually corrected to reflect the original.

Using Microsoft Word™ (2003), each consent form was evaluated for readability and the results printed. For the full study, the consent forms and their readability scores were be sorted into two categories of research based on risk: minimal risk (n = 30), and greater than minimal risk (n = 30). The pilot study analyzed only 10 consent forms from each risk category. Results were summarized into tabular format. Variables from the categories were compared with analysis of variance (ANOVA).

Consent form readability variables include the Flesch Reading Ease and Flesch-Kincaid grade level, words, characters, paragraphs, and sentences per document. All descriptive results were tabulated and sorted based on readability. Results were analyzed with SPSS version 12.0.

Expected Findings and Utility of Results

We expected to reject the alternate hypothesis and accept the null. From observation, military consent forms do not differ from those of the civilian sector. The results are quite predictable. What is more important is the implication of this conclusion.

In *Cantebury v. Spence* (1972), Judge Robinson briefly discussed the need for expert testimony in nondisclosure litigation. Despite the need for experts, it was lay testimony that "competently establish a physician's failure to disclose particular risk information, the patient's lack of knowledge of this risk, and the adverse consequences following the treatment." Judge Robinson's statement could be addressed through the readability of consent forms. If a consent form is worded in a manner that a lay person can understand, then the participant is more likely to understand the risks, benefits, and alternatives to the research procedures. Despite this landmark case in 1972, primary researchers have continued to author consent forms far beyond the ability of the average reader. Why has it not caused a widespread problem? If oncology consent forms, some in excess of 20 pages, are regularly signed, does the readability of these

complex forms really matter? What is the efficacy of the consent form in deference to the desperation of the subject?

This document has a readability score of 12.0 (see Appendix C).

Data

Figure 1 illustrates a typical readability statistic report provided by Microsoft Word™. The Flesch Reading Ease provides an integer value commensurate to the ease of reading. The higher the number, the easier the document is to read. The Flesch Reading Ease calculates its result datum using a mathematical function as follows:

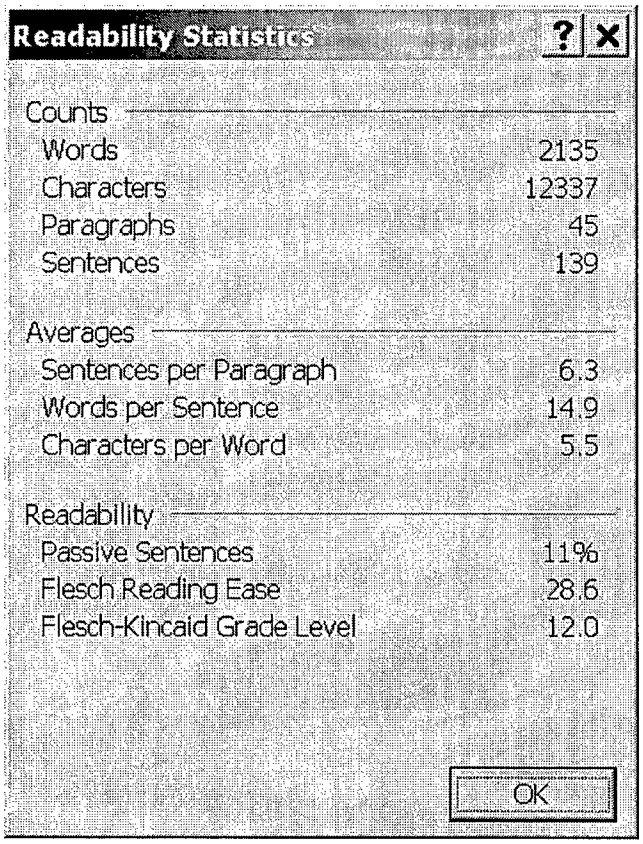
$[206.835 - (1.015 \times (avgwords / sentence)) - (84.6 \times (avgsyllables / word))]$.

The reading ease score of 28.6 is suboptimal. The aim is to maximize the score with a score of 65 interpreted as "plain English" (Gnome, 2003). As the score approaches 100, the ease of reading improves.

The Flesch-Kincaid Grade Level calculates a similar score, but instead of a reading ease, it presents the school grade that an individual would need to have reached to understand the document. The Flesch-Kincaid Grade Level calculates this datum as follows:

$[.39 \times (avgwords / sentence) + (11.8 \times (avgsyllables / word) - 15.59]$. The Flesch-Kincaid Grade Level of 12.0 means that in order for a reader to understand this document, he/she would have to be, at a minimum, a high school graduate. Because the Flesch-Kincaid Grade Level ranges from 1 to 12.0, a document written beyond the high school graduate education level would still be represented by a 12.0.

Figure 1: Readability statistics for a document, calculated by Microsoft Word™.



Source: Microsoft Office Word, 2003 (11.6113.5703).

Types of Data

The Flesch-Kincaid readability criterion provides two calculations: Flesch Reading Ease and Flesch-Kincaid Grade Level. There are four types of data, and these are depicted in Figure 2. Because each readability criterion provides data in tenths, the characteristics of the data match the interval classification. As a result, parametric tests may be used.

Figure 2: Types of Data

Type of Data	Characteristics of Data	Basic Empirical Operation	Example
Nominal	Classification but no order, distance, or origin	Determination of equality	Gender (male, female)
Ordinal	Classification and order but no distance or unique origin	Determination of greater or lesser value	Doneness of meat (well, medium well, medium rare, rare)
Interval	Classification, order, and distance but no unique origin	Determination of equality of intervals or differences	Temperature in degrees
Ratio	Classification, order, distance, and unique origin	Determination of equality of ratios	Age in years

Source: Cooper and Schindler (2003, p. 233).

Probability Sampling Design

Cooper and Schindler (2003) list five designs for probability sampling. Appendix B illustrates these designs. Mader and Playe's (1997) design for this study included three groups. We modified this study design to delineate two risk categories in accordance with the Common Rule and Army Regulation 40-38. The probability sample fits the *stratified* description. We divided our protocols into groups, or strata, and maintained equal sample sizes in each group.

Statistical Techniques

With interval data and parametric tests, the tests available to evaluate the data are the *t* or *Z*-test (parametric) and analysis of variance (ANOVA). Figure 3 depicts a method by which researchers can select the appropriate test for statistical analysis. This study used this figure to determine an appropriate statistical technique to evaluate the data.

Figure 3: Statistical Techniques

Measurement Level	One-Sample Case	Two-Samples Case: Related Samples	Two-Samples Case: Independent Samples	k-Samples Case: Related Samples	k-Samples Case: Independent Samples
Nominal	• Binomial • χ^2 One-sample	• McNemar	• Fisher exact test • χ^2 Two-samples test	• Cochran Q	• χ^2 for *k* samples
Ordinal	• Kolmogorov-Smirnov one-sample test • Runs test	• Sign test • Wilcoxon matched-pairs test	• Median test • Mann-Whitney U • Kolmogorov-Smirnov • Wald-Wolfowitz	• Friedman two-way ANOVA	• Median extension • Kruskal-Wallis one-way ANOVA
Interval and ratio	• *t*-test • Z test	• *t*-test for paired samples	• *t*-test • Z test	• Repeated-measures ANOVA	• One-way ANOVA • *n*-way ANOVA

Source: Cooper and Schindler (2003, p. 534).

General Linear Model Multivariate Analysis

Because our data are interval in nature, we can choose between nonparametric tests or stronger parametric tests, depending on the distribution of the data. If our data is normally distributed, the general linear model (GLM) multivariate analysis (version 12) is an appropriate parametric test. The following is a description of the GLM multivariate analysis, as explained in the help file of SPSS (version 12.0).

> The GLM multivariate procedure provides regression analysis and analysis of variance for multiple dependent variables by one or more factor variables or covariates. The factor variables divide the population into groups. Using this general linear model procedure, you can test null hypotheses about the effects of factor variables on the means of various groupings of a joint distribution of dependent variables. You can investigate interactions between factors as well

as the effects of individual factors. In addition, the effects of covariates and covariate interactions with factors can be included. For regression analysis, the independent (predictor) variables are specified as covariates.

Both balanced and unbalanced models can be tested. A design is balanced if each cell in the model contains the same number of cases. In a multivariate model, the sums of squares due to the effects in the model and error sums of squares are in matrix form rather than the scalar form found in univariate analysis. These matrices are called SSCP (sums-of-squares and cross-products) matrices. If more than one dependent variable is specified, the multivariate analysis of variance using Pillai's trace, Wilks' lambda, Hotelling's trace, and Roy's largest root criterion with approximate F statistic are provided as well as the univariate analysis of variance for each dependent variable. In addition to testing hypotheses, GLM Multivariate produces estimates of parameters.

We expect the means of the two groups to be normally distributed for all the dependent variables associated with each risk category.

Pilot Study

This pilot study was conducted jointly with CPT Mon under the direction of COL Lee Briggs, Preceptor for the residency portion of the Army-Baylor Program. The results are mirrored identically in CPT Mon's study. The purpose of conducting the pilot study was to verify the appropriateness of the procedure intended for use in both main studies, one of Army consent forms and the other of Air Force consent forms. At the time this pilot study was conducted, CPT Mon and I were only granted access to the Army's consent forms. The lessons

learned from the pilot study were incorporated into the main study to further increase validity and reliability of the results.

Data (n = 20) for medical research studies were entered into SPSS coding groups as dichotomous variables (1 or 0), and recording integer output for the Flesch Reading Ease and the Flesch-Kincaid Grade Level. Table 1 displays the data.

Table 1. Sample Data Set

Consent Forms	Risk Level (GTMR = 0, MR = 1)	Words	Characters	Paragraphs	Sentences	Avg Sentences per Paragraphs	Avg Words per Sentences	Avg Characters per Word	Passive Sentences	Flesch Reading ease	Flesch-Kincaid Grade Level
1	0	3887	19891	116	157	4.3	20.5	4.8	0.35	41.9	12.0
2	0	2929	14959	75	138	3.3	19.1	4.9	0.28	39.4	12.0
3	0	4343	22061	274	182	2.1	18.4	4.8	0.29	46.7	11.1
4	0	3997	19762	97	169	3.5	20.2	4.7	0.45	46.6	11.6
5	0	6528	33364	307	292	2.1	18.6	4.8	0.33	48.5	10.8
6	0	5288	27314	183	215	2.5	21.2	4.9	0.35	42.4	12.0
7	0	1881	9908	51	78	2.8	21.4	5.1	0.35	33.8	12.0
8	0	7815	39329	272	255	2.7	24.4	4.8	0.37	41.5	12.0
9	0	1631	8431	48	58	2.0	25.6	5.0	0.41	33.6	12.0
10	0	1596	8647	54	67	3.5	20.6	5.1	0.23	32.4	12.0
11	1	1,604	8753	52	70	2.4	21.2	5.2	0.00	28.4	12.0
12	1	918	4987	53	35	1.8	21.4	5.0	0.37	30.6	12.0
13	1	918	5067	53	32	2.0	21.5	5.2	0.21	28.6	12.0
14	1	1210	6731	30	44	3.6	22.0	5.0	0.31	28.9	12.0
15	1	2783	14749	86	113	3.6	19.8	4.9	0.35	39.9	12.0
16	1	1997	10742	56	70	2.4	23.9	5.1	0.20	27.4	12.0
17	1	1743	9265	64	67	2.9	18.9	5.0	0.25	37.0	12.0
18	1	2369	12423	79	88	2.9	19.9	4.9	0.43	38.8	12.0
19	1	1755	9087	63	71	1.9	22.4	4.9	0.16	35.4	12.0
20	1	1115	5926	40	43	2.3	22.8	5.2	0.13	30.0	12.0

Results of Pilot Study

The results of the pilot study are summarized in Table 2. Ten minimal risk (minimal risk variable equal to one) and ten greater than minimal risk (minimal risk variable equal to zero) consent forms were analyzed. As depicted in Table 2, the mean number of words for minimal risk and greater than minimal risk consent forms were 1,641.20 ±623.03 and 3,989.50±2101.9, respectively. The mean number of words per sentence for the minimal and greater than minimal risk consent forms was 21.38±1.52 and 21.0±2.36, respectively. Overall, the mean reading ease score was 36.59±6.66 for all 20 forms. The reading scores for minimal risk consent forms was 32.5±4.76, and the mean reading score for greater than minimal risk consent forms was 40.68±5.82. The overall mean Flesch-Kincaid grade level was calculated at11.88±.33 for all 20 forms while the mean grade level for minimal risk was 12.0±0 and 11.7±.45 for greater than minimal risk. As depicted in Table 3, results showed seven items of significance. Each dependent variable increased along with risk. The following variables were significant at $P < .01$: words ($F = 11.47$), characters ($F = 11.08$), sentences ($F = 13.86$), and Flesch Reading Ease ($F = 11.83$). The following dependent variables were significant at $P < .05$: paragraphs ($F = 7.50$), average characters per word ($F = 6.47$), and passive voice ($F = 4.86$).

Lessons Learned

At the beginning of the study, the Army, Navy, and Air Force were contacted about participating. Initially, neither the Navy nor the Air Force provided any consent forms. The Director, Clinical Investigation and Responsible Conduct of Research for the U.S. Navy responded to our request for consent forms with extreme trepidation. The contact explained that the author of each study would have to be contacted and give permission to analyze the study's consent form. Further, the director intended to redact all information about the origin of the

study, the principle investigator, and any contact information. After agreeing to these terms, the director still failed to provide any data. The Division Chief for Biomedical Research and Compliance Division for the U.S. Air Force appeared cooperative to our initial requests, but consent forms were not provided. As a result, the pilot study was conducted using only Army consent forms. A few Air Force consent forms arrived after the Army study was complete. It was decided to use service-specific consent forms in distinct studies.

The Mader and Playe (1997) study which we originally planned to model chose a descriptive, two-factor research design to compare the readability indices of consent forms (n = 94) over three categories separated by level of risk. The Common Rule and Army Regulation 40-38 only delineate risk into two categories: minimal risk and greater than minimal risk. Creating a third category would necessitate utilizing the opinions of IRB members and research experts to assist in separating the available consent forms into three instead of two risk categories. To eliminate any human bias or error, we chose to study the consent forms based on risk specifically defined in The Common Rule and Army regulations.

As noted previously, Microsoft Word™ computes the Flesch-Kincaid Grade Level between a range of 1.0 to 12.0. Because the Flesch-Kincaid Grade Level in this program does not calculate grade levels above 12.0, a document written beyond that level would still be represented by a 12.0. Expectations are for the grade level of many of the protocols analyzed in this study to exceed the maximum score of 12.0 grade level. Since this study seeks to determine the magnitude of the number of informed consent forms that exceed the 6^{th} grade level, the limitation of the measurement tool is acceptable for this study's purpose. If another software program were utilized to calculate the average number of syllables per word for each consent form, the Flesch-Kincaid Grade Level could be calculated manually to validate our notion. The

lower risk consent documents were coded as one and the higher risk as zero. This is counterintuitive. Coding for the main study (n = 60) was reversed: coding minimal risk as zero and greater than minimal risk as one.

Table 2. Descriptive Statistics

Minimal Risk		Words	Characters	Paragraphs	Sentences	Avg Sentences per Paragraphs	Avg Words per Sentences	Avg Characters per Word	Passive Sentences	Flesch Reading ease	Flesch-Kincaid Grade Level
0	Mean	3989.50	20366.60	147.70	161.10	2.8800	21.0000	4.8900	.3410	40.6800	11.7500
	N	10	10	10	10	10	10	10	10	10	10
	Std. Deviation	2101.900	10533.893	102.716	79.090	.75542	2.35938	.13703	.06367	5.82348	.44535
1	Mean	1641.20	8773.00	57.60	63.30	2.5800	21.3800	5.0400	.2410	32.5000	12.0000
	N	10	10	10	10	10	10	10	10	10	10
	Std. Deviation	623.034	3224.843	16.608	25.404	.65286	1.51570	.12649	.12853	4.76049	.00000
Total	Mean	2815.35	14569.80	102.65	112.20	2.7300	21.1900	4.9650	.2910	36.5900	11.8750
	N	20	20	20	20	20	20	20	20	20	20
	Std. Deviation	1930.748	9636.336	85.233	76.064	.70420	1.93986	.14965	.11126	6.66388	.33226

Table 3. Results based on category of risk.

Source	Dependent Variable	Type III Sum of Squares	df	Mean Square	F	Sig.
Risk_MR_1	Words	27572564.5	1	27572564.45	11.474	.003
	Characters	672057805	1	672057804.8	11.075	.004
	Paragraphs	40590.050	1	40590.050	7.498	.014
	Sentences	47824.200	1	47824.200	13.861	.002
	avg_spp	.450	1	.450	.903	.355
	avg_wps	.722	1	.722	.184	.673
	avg_cpw	.113	1	.113	6.470	.020
	passive	.050	1	.050	4.860	.041
	Reading_Ease	334.562	1	334.562	11.827	.003
	Grade_level	.313	1	.313	3.151	.093

Main study of Air Force Consent Forms

Institutional Review Boards from the U.S. Air Force graciously provided consent forms used in USAF human research. These consent forms were provided in Microsoft Word. This electronic format considerably simplified the method as it removed human intervention to correct errors imposed by the OCR process. The Air Force IRBs provided consent forms from both risk categories: minimal risk (n = 14) and greater than minimal risk (n = 7). Incorporating the lessons learned from the pilot study, the main study coded the risk categories more logically; minimal risk was coded as zero and greater than minimal risk was coded as one. Data were interval in nature and stronger parametric tests were appropriate for evaluation. Like the Pilot Study, a GLM test was used to conduct a multivariate analysis. Statistics were compiled in SPSS version 12.0. The data for the main study are depicted in Appendix D.

Results of Main Study

The results of the main study are summarized in Table 4. Close comparison between the pilot and main studies should reveal similarities and continuity. Similar to the pilot study, four of the ten dependent variables were significant ($P < .01$) based on level of risk. As depicted in Table 4, the mean number of words for minimal risk and greater than minimal risk consent forms were 2,211.14 $\pm$ 584.67 and 3,297.14 $\pm$ 741.59 respectively. The pilot study revealed 12% more words overall. The mean number of characters for the minimal and greater than minimal risk consent forms were 11,551.00 $\pm$ 3,146.98 and 17,183.71 $\pm$ 3,391.97 respectively. The pilot study reflected 13% more characters overall. The mean number of paragraphs for the minimal and greater than minimal risk consent forms in the USAF were 92.64 $\pm$ 15.20 and 118.57 $\pm$ 27.44 respectively. This showed a 10%decrease in paragraphs from the pilot study overall. The mean number of sentences for the minimal and greater than minimal risk consent forms were 86.29 $\pm$

23.61 and 132.86 $\pm$ 30.48 respectively. The main study showed a 4% decrease in sentences from the pilot study overall. Overall, the mean Flesch-Kincaid Grade Levels was 11.83 $\pm$ .35 for all 21 forms, which illustrated a .4% improvement in readability. The overall mean Flesch Reading Ease score was calculated at 39.97 $\pm$ 5.72 for all 21 forms, which was an 11% improvement in readability. As depicted in Table 5, results showed four items of significance, illustrating a direct relationship with the level of risk. These variables were significant at $P < .01$: words ($F = 13.51$), characters ($F = 14.22$), paragraphs ($F = 7.93$), and sentences ($F = 15.00$).

Table 4: Descriptive Statistics for the main study

Descriptive Statistics

	risk_cat	Mean	Std. Deviation	N
words	MR	2211.14	584.667	14
	GTMR	3297.14	741.585	7
	Total	2573.14	813.861	21
char	MR	11551.00	3146.982	14
	GTMR	17183.71	3391.967	7
	Total	13428.57	4158.363	21
parag	MR	92.64	15.199	14
	GTMR	118.57	27.440	7
	Total	101.29	23.085	21
sentence	MR	86.29	23.607	14
	GTMR	132.86	30.482	7
	Total	101.81	33.868	21
avg_s_pr	MR	2.3357	.48454	14
	GTMR	2.5286	.48206	7
	Total	2.4000	.48062	21
avg_w_s	MR	21.5857	2.34811	14
	GTMR	21.9429	2.07031	7
	Total	21.7048	2.21348	21
avg_c_w	MR	4.8786	.16723	14
	GTMR	4.8714	.18898	7
	Total	4.8762	.17001	21
passive	MR	.2307	.07043	14
	GTMR	.2329	.07544	7
	Total	.2314	.07023	21
fl_re	MR	39.9571	6.37081	14
	GTMR	39.9857	4.60631	7
	Total	39.9667	5.72253	21
fk_gl	MR	11.7429	.40897	14
	GTMR	12.0000	.00000	7
	Total	11.8286	.35234	21

Table 5: Results based on category of risk

Source	Dependent Variable	Type III Sum of Squares	df	Mean Square	F	Sig.	Partial Eta Squared
risk_cat	words	5503848.000	1	5503848.000	13.505	.002	.415
	char	148061528	1	148061527.7	14.224	.001	.428
	parag	3137.357	1	3137.357	7.926	.011	.294
	sentence	10121.524	1	10121.524	15.001	.001	.441
	avg_s_pr	.174	1	.174	.742	.400	.038
	avg_w_s	.595	1	.595	.116	.737	.006
	avg_c_w	.000	1	.000	.008	.930	.000
	passive	.000	1	.000	.004	.949	.000
	fl_re	.004	1	.004	.000	.992	.000
	fk_gl	.309	1	.309	2.696	.117	.124

Discussion

Mader and Playe (1997) found significance between reading ease and reading level based on three risk categories. This study chose the risk categories defined by the Common Rule: Minimal Risk and Greater Than Minimal Risk. Among the 10 dependent variables in this study, significance was not found in either the Flesch Reading Ease or the Flesch-Kincaid Grade Level, but there was significance in four other variables.

The differences between the two studies could be explained by the standardized form required for use within the areas of influence for each regional IRB. One region allowed what most would consider to be a free-flowing text document. Two other regions used a tabular format illustrated in Appendix E. The restriction inherent to a standard form may have normalized the data between the risk categories for the Flesch Reading Ease and the Flesch-Kincaid reading level. The Flesch-Kincaid grade level for the tabular form is 120. This statistic disadvantages researcher in conveying a simple message to the study participant. To reduce this grade level, and simplify the consent form, the researcher must write a lengthy, simply-worded document. Examinations of the cognitive effect of length are not conducted in this study, but stand as a possibility for ones in the future.

Another independent variable may be the location of the IRB and resulting consent forms for that region. A subsequent study may want to delineate between regions and run the statistics again to determine if differences in the form cause readability to change. Another study may want to subdue the effects of the form by stripping out the verbiage about the study and pasting to a free-flowing document. This step would allow the readability algorithms to evaluate the verbiage instead of the form, but this step may also falsely measure the effects of the form on the reader. The form may do more than change the calculation of the algorithm. A further study on

the cognitive process surrounding the informed consent process could look at such an effect. A direct comparison between this study and that of Mader and Playe (1997) would have to standardize the measurements between the samples. Additionally, because this study chose to use the definition of risk as defined by the Common Rule, a comparison between the studies would require that both studies use the same risk categories.

Mon (Mar, 2005) evaluated the readability of U.S. Army consent forms (n=60). Her results confessed significance on six of ten dependent variables: number of words ($F = 20.85$, $P < .01$), number of characters ($F = 19.14$, $P < .01$), number of paragraphs ($F = 14.32$, $P < .01$), number of sentences ($F = 20.85$, $P < .01$), Flesch Reading Ease ($F = 14.23$, $P < .01$), and average characters per word ($F = 10.19$, $P < .05$). Comparing the results between services, the consent forms in both risk categories in the Army used .05 more passive voice than those in the AF ($F = 4.41$, $P < .05$). When the data sets from both services were combined, the data confessed significance ($P < .01$) between risk categories in four of the ten dependent variables: words ($F = 17.01$), characters, ($F = 16.96$), paragraphs ($F = 9.10$), and sentences ($F = 18.03$). When comparing the data between services and risk categores, one dependent variables was significant: Flesch-Kincaid Grade Level ($F = 4.67$, $P < .05$). Other than the dependent variables listed above, the consent forms used in the Army and Air Force were not statistically different. Overall, those used in the Army contained more words, characters, paragraphs, sentences, average sentences per paragraph, and average characters per word ($P > .05$).

The results of this study should not be surprising. Mader and Playe (1997) found the readability of consent forms in human research in the civilian sector decreased as the riskiness of the study increased. Few should be surprised that the public sector would not differ. The more salient point of the studies in both the public and private sectors is the implication on respect for

autonomy. When consent forms are written with complexity above that which subjects can understand, the results run counter to the intent. If a subject cannot comprehend the risks, benefits, and alternatives of a study, then principle investigators do not respect the autonomy of the subjects.

Office for the Protection from Research Risk (2003) states, "Informed consent is a process, not just a form." The consent form is part of the process of informing the subject, but it cannot not stand alone. When possible, investigators should simplify language in the consent form and provide sufficient venues to explain any verbiage written above "lay language," which for the purposes of this study is sixth grade.

Conclusion

Despite the differences between this study and that of Mader and Playe (1997), the conclusions are similar. Based on the findings of this study, consent forms for human research in the Air Force are written too complex to be understood by the average reader. The Flesch Reading Ease means that the higher the score (up to 100) the easier the document is to read. An average score of 39.97 means that a significant portion of the average population cannot easily read and interpret the consent forms. The average Flesch-Kincaid Grade Level for all 21 consent forms was 11.83. Based on this study's threshold of the sixth grade reading level, consent forms for human research in the Air Force are written almost twice as high as a lay person can understand.

References

Albarelli, H. & Kelly, J. (2001, July 6). New evidence in Army's scientist's death [Electronic Version]. *World Net Daily.* Retrieved November 30, 2003 from http://www.worldnetdaily.com/news/aricle.asp?ARTICLE_ID=23489.

Arthur, V. (1995). Written patient information: a review of the literature. *Journal of advanced nursing.* 21(6), pp. 1081 – 1086.

Beauchamp, T. & Childress, J. (2001). *Principles of Biomedical Ethics* (5th ed.). New York: Oxford University Press.

Canterbury v. Spence, 464 F.2d 772 (D.C. Cir. 1972).

Cooper D., & Schindler P. (2003). Business research methods. New York: McGraw-Hill.

Ferguson, P.R., (2002). Patients' perceptions of information provided in clinical trials. *Research ethics.* 28, pp.45 – 48.

Glazer-Waldman, W., Hall, K., & Weiner, M., (1985). Patient education in a public hospital. *Nursing research.* 34(3), pp. 184 – 185.

Gnome (2003). *User and readability consideration for technical documentation.* Retrieved November 1, 2003, from http://developer.gnome.org/documents/style-guide/usability-readability.html.

Howard, J., & DeMets, D. How informed is informed consent? The BHAT experience. *Controlled clinical trials.* 1981(2), 287 – 303.

Johnson, K. (2004). Readability. Retrieved August 6, 2004 from http://www.timetabler.com/reading.html

Jones, J. (1993) *Bad blood: The Tuskegee syphilis experiment.* New York, The Free Press

Lee, P. (1999, January). Why literacy matters: Links between reading ability and health. Why literacy matters: Links between reading ability and health. *American Medical Association*, 117, 100-103.

Limitation On Use of Humans as Experimental Subjects, 10 U.S.C. 980. Retrieved April 4, 2005 from http://www.dtic.mil/biosys/downloads/title10.pdf

Luce, J. (2003). Is the concept of informed consent applicable to clinical research involving critically ill patients? *Critical Care Medicine.* 31(3) supplement, pp. S153 – S160.

Mader, T., & Playe, S. (1997). Emergency medicine research consent form readability assessment. *Annals of emergency medicine.* 29(4), pp. 534 – 539.

Matot, E., Pizov, R., & Sprung, C. (1998). Evaluation of institutional review board review and informed consent in publications of human research in critical care medicine. *Critical Care Medicine.* 26(9), pp. 1488 – 1489.

Microsoft. (2003). Microsoft Word 2000 (9.096926 SP-3). Belleview, WA: Microsoft Corporation.

National Defense, 32 C.F.R. § 219 (2004).

National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research (1979). *The Belmont report:.ethical principles and guidelines for the protection of human subjects of research.* Retrieved November 30, 2003 from http://www.hhs.gov/ohrp/humansubjects/guidance/belmont.htm

Ott, B., & Hardie, T. (1997). Readability of advance directive documents. *The Journal of Nursing Scholarship.* 29(1), pp. 53 – 57.

Paasche-Orlow, M., Taylor, H., & Brancati, F. (2003). Readability standards for informed-consent forms as compared with actual readability. *The New England Journal of Medicine.* 348(8), pp. 721-726.

Public Welfare, 45 C.F.R. § 46 (2004).

Schloendorff v. Society of New York Hospital, 211 NY 125, 105 NE 92:1914.

Standler, R. (1997).*Nonconsensual Medical Experiments on Human Beings.* Retrieved November 30, 2003 from http://www.rbs2.com/humres.htm.

The United Nations General Assembly. (1948). *Universal Declaration of Human Rights.* Retrieved November 30, 2003 from http://www.un.org/Overview/rights.html.

U. S. Army: Clinical Investigation Program: Army Regulation 40-38. Washington, DC, Department of the Army, 1989.

U. S. Department of Health and Human Services (2004) *Institutional review board guidebook.* Retrieved November 8, 2003, from http://www.hhs.gov/ohrp/irb/irb_guidebook.htm .

United States v. Karl Brandt, et al., The Medical Case Trial, Trials of War Criminals before the Nuremberg Military Tribunals under Control Council Law No. 10. Nuremburg (1950).

University of Utah (2004a). *The Jewish chronic disease hospital study.* Retrieved November 30, 2003 from http://www.bioen.utah.edu/faculty/sri/LAB1_handout.htm.

University of Utah. (2004b). *The Smog readability formula.* Retrieved November 1, 2003, from http://www.med.utah.edu/pated/authors/readability.html

University of Utah. (2004c). *The Willowbrook study.* Retrieved November 1, 2003, from http://www.bioen.utah.edu/faculty/sri/LAB1_handout.htm.

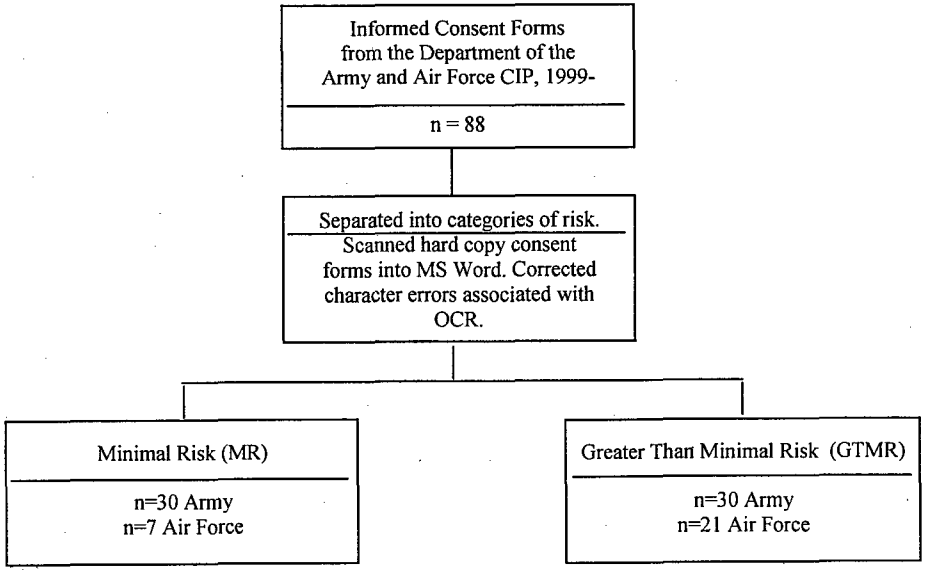
Walmsley, S., & Allington, R.(1982). Reading abilities of elderly persons in relation to the difficulty of essential documents. *Gerontologist.* 22(1), pp. 36 – 38.

Woodward, B. (1999). Challenges to human subject protections in US medical research. *Journal of the American Medical Association*, 282, pp. 1947-1952.

Zucker, K., & Boyle, M. (2000). *Health Law for Federal Sector Administrators (2 vol, 8th ed.).* AMEDDC&S.

Appendix A

Research Work Flow Diagram



Appendix B

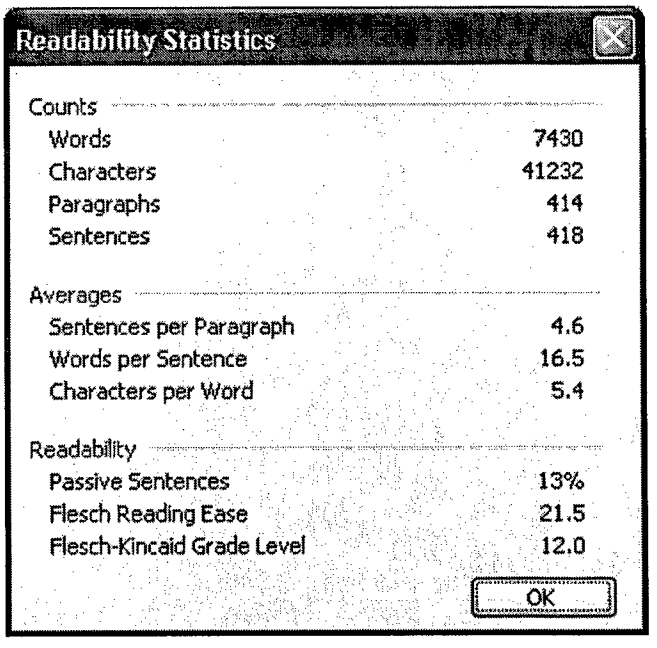
Comparison of Probability Sampling Designs

Type	Description	Advantages	Disadvantages
Simple random	Each population element has an equal chance of being selected into the sample. Sample drawn using random number table/generator.	Easy to implement with automatic dialing (random digit dialing) and with computerized voice response systems.	Requires a listing of population elements. Takes more time to implement. Uses larger sample sizes. Produces larger errors. Expensive.
Systematic	Selects an element of the population at a beginning with a random start and following the sampling fraction selects every *k*th element.	Simple to design. Easier to use than the simple random. Easy to determine sampling distribution of mean or proportion. Less expensive than simple random.	Periodicity within the population may skew the sample and results. If the population list has a monotonic trend, a biased estimate will result based on the start point.
Stratified	Divides population into subpopulations or strata and uses simple random on each strata. Results may be weighted and combined.	Researcher controls sample size in strata. Increased statistical efficiency. Provides data to represent and analyze subgroups. Enables use of different methods in strata.	Increased error will result if subgroups are selected at different rates. Expensive. Especially expensive if strata on the population have to be created.
Cluster	Population is divided into internally heterogeneous subgroups. Some are randomly selected for further study.	Provides an unbiased estimate of population parameters if properly done. Economically more efficient than simple random. Lowest cost per sample, especially with geographic clusters. Easy to do without a population list.	Often lower statistical efficiency (more error) due to subgroups being homogeneous rather than heterogeneous.
Double (sequential or multiphase)	Process includes collecting data from a sample using a previously defined technique. Based on the information found, a subsample is selected for further study.	May reduce costs if first stage results in enough data to stratify or cluster the population.	Increased costs if indiscriminately used.

Source: Cooper and Schindler (2003, p. 199).

Appendix C

Readability Score for This Study



Appendix D

Data From the Main Study

Consent Forms	Risk (GTMR=1, MR=0)	Words	Characters	Paragraphs	Sentences	Avg Sentences per Paragraphs	Avg Words per Sentences	Avg Characters per Word	Passive Sentences	Flesch Reading ease	Flesch-Kincaid Grade Level
1	1	2017	11725	97	88	2.2	19.5	5.2	0.26	32.9	12.0
2	1	3182	16515	143	137	2.0	19.8	4.8	0.29	42.8	12.0
3	1	3748	18367	104	143	3.1	23.8	4.6	0.29	46.9	12.0
4	1	3048	15719	95	121	2.8	22.6	4.8	0.19	41.3	12.0
5	1	2977	15699	99	106	2.5	25.0	5.0	0.15	35.6	12.0
6	1	3795	20160	166	158	2.0	20.6	4.9	0.13	40.6	12.0
7	1	4313	22101	126	177	3.1	22.3	4.8	0.32	39.8	12.0
1	0	1804	8805	88	80	1.8	18.9	4.6	0.18	47.9	11.2
2	0	1302	6795	72	54	1.6	18.6	4.9	0.33	42.4	11.9
3	0	1662	8334	96	68	1.5	19.0	4.7	0.23	47.7	11.1
4	0	2080	10114	82	95	2.3	18.8	4.7	0.34	48.9	11.0
5	0	1600	8702	79	63	2.5	20.5	5.1	0.31	37.2	12.0
6	0	2892	14520	126	119	2.5	21.0	4.6	0.33	50.3	11.2
7	0	1917	10177	83	66	2.2	23.9	5.0	0.21	33.6	12.0
8	0	2253	11732	87	84	2.8	22.7	4.8	0.13	40.4	12.0
9	0	2267	12165	91	73	2.2	25.9	5.0	0.21	33.6	12.0
10	0	2054	10938	87	72	2.1	24.3	5.0	0.15	35.0	12.0
11	0	2071	11109	85	87	2.5	20.4	5.0	0.16	35.4	12.0
12	0	3364	17597	99	138	3.2	21.7	4.9	0.24	39.1	12.0
13	0	2728	14749	101	103	2.9	23.1	5.0	0.20	32.4	12.0
14	0	2962	15977	121	106	2.6	23.4	5.0	0.21	35.5	12.0

Appendix E

Blank Consent Form from the U.S. Air Force

INFORMED CONSENT DOCUMENT

XXTH MEDICAL GROUP
Any AF Medical Center
1000 West East Road
Named AFB, ST xxxxx

Privacy Act of 1974 and Health Insurance Portability And Accountability Act (HIPAA) applies. DD Form 2005 filed in and Notice of Privacy Practices label contained on the outside of Clinical/Medical Records.

PRIVACY ISSUES: *Protected health information (PHI) is any health information about you that can reasonably be used to identify you by the person to whom it is provided. The people who are conducting the study (the "Researchers") may need to look at your medical and study records that contain PHI. Records of your participation in this study may only be disclosed in accordance with federal law, including the Federal Privacy Act, 5 USC 552, HIPAA, and their implementing regulations. DD Form 2005 contains the Privacy Act Statement for the records. Government agencies that make rules and policies about how research is done, including the Office for Human Research Protections (OHRP) and the Food and Drug Administration (FDA), have the right to review these records, if applicable.*

TITLE OF STUDY

INVESTIGATORS' NAMES, DEPARTMENTS, PHONE NUMBERS

The principal investigators will be available to answer any questions concerning procedures throughout this study.
Air Force Surgeon General Office Principal Co-Investigators:

INTRODUCTION

It is important that you read and understand several general principles that apply to all who take part in research studies: (a) taking part in the study is entirely voluntary; (b) personal benefit may not result from taking part in the study, but knowledge may be gained that will benefit others; (c) you may withdraw from the study at any time without penalty or loss of any benefits to which you are otherwise entitled. The nature of the study, the risks, inconveniences, discomforts, and other pertinent information about the study are discussed below. If you have personal, religious or ethical beliefs, which you think, might limit the types of medical treatment (for example, blood transfusions) that you would agree to receive; you should discuss them fully with your physician(s) before entering this study. You are urged to discuss any questions you have about this study with your doctor(s) and/or the clinic staff members.

PURPOSE OF STUDY

(This section will explain the nature, purpose(s), approximate number of subjects, and the duration of participants' involvement.)

You, _____ (SSN: - -), understand that you are being asked to participate in a research study.

You have been selected to participate in this study because you have

PROCEDURES

(This section will explain all procedures and the purpose of the procedures to be undergone as part of this study. Any experimental procedures will be explained as such.)

PROCEDURES

BENEFITS

Participation in this study may or may not benefit you directly

OR

(For minor subjects)

The purpose of this study is to benefit you. At this time, the investigator(s) does not know if the most commonly accepted treatments achieve the best possible results. This study has been designed to learn if the new treatment is as good as or better than the most commonly accepted treatments. You understand though that participating in this study does not guarantee benefit better than standard treatment.

ALTERNATIVES

(This section will explain your alternative treatment possibilities)

Choosing not to participate in this study is your alternative to volunteering for the study, however you will still receive standard treatment for your condition. You will not receive any compensation (money) for participating in this study.

RISKS/INCONVENIENCES

(Any discomfort , risks, inconveniences caused from procedures or drugs used that may be expected from participation in this study.)

EVENT OF INJURY

You understand that your entitlement to medical and dental care and/or compensation in the event of injury is governed by federal laws and regulations, and if you have questions about your rights or if you believe you have received a research-related injury, you may contact _____, or the Principle Investigator of this study at _____. Your entitlement to medical and dental care and/or compensation in the event of injury is governed by federal laws and regulations. If you believe you have received a research-related injury, you may contact the Principal Investigator of this study at _____. In addition, if you have any comments, questions, concerns or complaints about your rights as a research subject, you may contact the (insert "Customer Subjects Representative" or "Institutional Review Board" and the phone number; you should get this from your local IRB).

OCCURRENCE OF UNANTICIPATED EVENT

If an unanticipated event occurs which may affect your willingness to participate in this study, you will be notified immediately. If you are not competent at the time to understand the nature of the event, this information will be brought to the attention of your next of kin.

CONFIDENTIALITY AND PROTECTED HEALTH INFORMATION (PHI)
(If Applicable-Please Complete All Blanks)

We will not use or disclose your records in any ways other than the ways we describe in this form, and we will keep your records private to the extent allowed by law.

Under the Health Insurance Portability and Accountability Act (HIPAA), a federal law enacted to protect the privacy of your protected health information (PHI), before we can use or disclose your PHI, we must provide you with information about what PHI will be used and how it will be used and disclosed.

Your protected health information that may be used and disclosed in this study includes:
- Demographic Information: i.e., age, sex, race, etc.
- Information about your health and your illness related to the infectious disease process
- Laboratory results

Your protected health information will be used for the purposes described under the section of this document entitled "DESCRIPTION/PURPOSE OF RESEARCH. In addition, your protected health information, and the samples collected for this study will be used for future research on improving methods of diagnosing _____. Your specimen and research-related health information (as it relates to the infectious process) will be assigned a unique code and stripped of your personal identifiers (name, social security, address, and date of birth). The key to linking your code with your personal identity will be protected under lock and key by an investigator at your place of care and by the Headquarters United States Air Force Surgeon General Director of Modernization.

The disclosure of your protected health information is necessary in order to be able to conduct the research project described. Records of your participation in this study may only be disclosed in accordance with federal law, including the Federal Privacy Act, the Health Insurance Portability and Accountability Act of 1996, 5 U.S.C.552a, and its implementing regulations. DD Form 2005, Privacy Act Statement - Military Health Records, contains the Privacy Act Statement for the records. Note: Protected health information of military service members may be used or disclosed for activities deemed necessary by appropriate military command authorities to ensure the proper execution of the military mission. In addition, complete confidentiality cannot be promised, particularly for military personnel, because information regarding your health may be required to be reported to appropriate public health authorities.

By signing this authorization, you give your permission for information gained from your participation in this study to be published in medical literature, discussed for educational purposes, and used generally to further medical science. You will not be personally identified; all information will be presented as anonymous data.

If you decide to participate in this research, then you will be agreeing to let the Researchers and any other persons, companies or agencies described below use and share your PHI for the study in the ways that are set forth in this section, so please review this section very carefully.

The Principal Investigator may use and share your health information with:
- Malcolm Grow Medical Center, IRB, Andrews Air Force Base, MD
- Government representatives, as required by law
- U.S. Food & Drug Administration (FDA),
- Department of Defense representatives
- Office of the Air Force Surgeon General/ Modernization (SGR) Falls Church, VA
- Naval Research Lab, Washington DC
- Bolling Air Force Base (BAFB) Medical Clinic, Washington DC
- Pentagon Flight Clinic (DeLorenzo Clinic), Arlington, Virginia

- Walter Reed Army Medical Center, Washington DC
- National Naval Medical Center, Bethesda, Maryland
- Joint Program Execution Office for Chemical Biological Defense, Falls Church, VA
- Naval Health Research Center
- Air Force Institute for Operational Health
- Midwest Research

The researchers and the Air Force SGR agree to protect your health information by using and disclosing it only as permitted by you in this authorization and as directed by state and federal law. If your protected health information is disclosed to anyone outside of this study, the information may no longer be protected under this authorization.

You do not have to sign this authorization. If you decide not to sign the Authorization, it will not affect your treatment, payment or enrollment in any health plans or affect your eligibility for benefits. By not signing, you may not be allowed to participate in the research study.

Note: rational it is repeated below
Your Right Under HIPAA to Revoke Your Authorization: Giving the researchers your authorization to use and share your PHI is voluntary. At any time, you may choose to revoke your authorization for the researchers to use and share your PHI. If you revoke your authorization, the researchers may no longer be able to provide you with any research-related treatment, but your revocation will not otherwise affect your current or future health care. Further, if you revoke your authorization, there will be no penalty or loss of any benefits to which you are otherwise entitled.

If you decide you want to revoke your PHI authorization, prepare and sign a revocation letter. Forward the letter to the Principal Investigator. Once we receive your written revocation of your authorization to use your PHI, we will not make any other use of your PHI or share it with anyone else, except as follows:

(a) we will let any other previously identified parties know that you have revoked your authorization;
(b) we will not ask any identified parties to return any data that we provided to it/them before you revoked your authorization;
(c) and, even after we receive your revocation, we will still provide them and any other parties to whom we stated that we would disclose data with any data that is necessary to preserve the integrity of the research study, and we will provide any governmental or other MDG/CC approved agency with any data that they may need in order to comply with/or investigate adverse events or non-compliance with any applicable laws or instructions.

Personal Representative: I certify that I _____, am over 18 years of age and that I am the personal representative of _____ ("Participant"), a person over 18 years of age, who has been invited to participate in this study but who is unable to sign this form due to physical or mental incapacity. Note rational it is already stated above

I further certify that I have full legal authority to make decisions concerning the participant, including decisions regarding health care and health care information.

PHI May be Re-disclosed: If we disclose your PHI to one of the other parties described above, that party might further disclose your PHI to another party. After the study is concluded and the data has been transmitted to the national agency sponsoring the study, the responsibility of DGMC is ended.

Expiration Date or Event: There is no expiration date for this authorization to use your protected health

information.

DECISION TO PARTICIPATE

VOLUNTARY PARTICIPATION:

The decision to participate in this study is completely voluntary on your part. No one has coerced or intimidated you into participating in this project. You are participating because you want to. The Principal Investigator or one of his/her associates has adequately answered any and all questions you have about this study, your participation, and the procedures involved. If significant new findings develop during the course of this study that may relate to your decision to continue participation, you will be informed.

You may withdraw this consent at any time and discontinue further participation in this study without affecting your eligibility for care or any other benefits to which you are entitled. Should you choose to withdraw, you must notify the principal investigator. Your decision will not affect your eligibility for care or any other benefits to which you are entitled. Because the key linking your code to your personal identity will be deleted upon completion of the study the investigators will not be able to identify your specimen. Therefore, you will not be able to withdraw your specimen once the study is completed. You will be able to withdraw your specimen during the study.

The investigator of this study may terminate your participation in this study at any time if it is in your best interest.

Your consent to participate in this study is given on a voluntary basis. All oral and written information and discussions about this study have been in English, a language in which you are fluent.

I have read all of the above. My questions have been answered to my satisfaction. I am willing to take part in this study. After I sign this form, I will receive a copy.

Your signature below indicates your willingness to participate in this research study and serves as your consent to release your protected health information.

Subject's Printed Name	Subject's SSN	
Subjects Address (street, city, state, zip)	Subject's Date of Birth	Date
Subject's Signature	FMP	Sponsor's SSN

Printed Name of Advising Investigator	Advising Investigator's Phone No	Date
Advising Investigator's Signature		Printed Name of Witness
Witness's Signature	Witness's SSN	Date

Distribution:
(1) Clinical Investigation Facility (60MDSS/SGSE); [original]
(2) Research Volunteer;
(3) Volunteer's Outpatient Medical Record, (permanently maintained);
(4) Principal Investigator.

* FMP (Family Member Prefix) such as 20 - sponsor, 30 - dependent spouse, 01 - first child, etc...